



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Jack I. Shugart
Serial No. : 10/764,222
Filing Date : January 23, 2004
Title : INJECTABLE EUTHANASIA COMPOSITIONS THAT INCLUDE
A TASTE AVERSIVE AGENT

Group/Art Unit : 1614
Examiner : Leslie A. Royds
Confirmation No. : 9135

Atty. Docket No. : 506401.0059

DECLARATION OF JACK I. SHUGART UNDER 37 C.F.R. § 1.132

I hereby declare as follows:

1. My name is Jack I. Shugart. I received both a B.S. in zoology and an M.S. in veterinary medical entomology from the University of Wyoming in Laramie, Wyoming. I received a Ph.D. in veterinary medical entomology from the University of Nebraska in Lincoln, Nebraska.
2. I have over 26 years of industry experience in veterinary pharmaceutical research and overseeing the making of pharmaceuticals for veterinary use. I am currently Vice President of Product Development for IVX Animal Health, Inc., the assignee of the above-referenced application.
3. I am the inventor of the above-referenced application.
4. I am aware of U.S. Patent No. 5,290,775 to Sawyer et al. (Sawyer '775 patent), U.S. Patent No. 5,720,951 to Baker (Baker), U.S. Patent Application Publication No. 2003/0064099 to Oshlack et al. (Oshlack), U.S. Patent No. 4,005,038 to Minkoff (Minkoff), U.S. Patent No. 5,962,566 to Komer (Komer), and U.S. Patent No. 5,281,611 to Sawyer et al. (Sawyer

'611 patent). I also am aware of the February 9, 2006 Office Action from the Patent Office that cites these references and rejects the claims in the above-referenced patent application.

5. One of ordinary skill in the art would not be motivated to make a euthanasia formulation containing a taste aversive agent, as claimed in the above-referenced application, by following the teachings of the Sawyer '775 patent, Baker, Oshlack, Minkoff, Komer and the Sawyer '611 patent alone or in combination.

6. When I initially conceived the idea of adding a taste aversive agent to an euthanasia formulation, I had concerns whether the taste aversive agent would be chemically compatible with the euthanasia formulation and whether the resulting formulation would be chemically stable.

7. More specifically, one concern was that after the mixture containing the euthanasia formulation and the taste aversive agent remained in a jar or vial for an extended period of time, the mixture would separate thus not allowing a correct dosage of the euthanasia formulation to be measured.

8. One compatibility concern was that the taste aversive agent would interfere with the euthanasia formulation so as to diminish the effectiveness of the formulation.

9. Another compatibility concern was that the taste aversive agent would interfere with the lidocaine in the euthanasia formulation so as to deactivate it and cause the animal being euthanized additional pain.

10. In fact, in attempting to obtain FDA approval for a euthanasia formulation that includes a taste aversive agent, the FDA also was concerned that the taste aversive agent would cause additional pain to the animal being euthanized. Therefore, the FDA required additional testing to be done to show that additional pain was not caused.

11. Only after product testing could the conclusion be made that mixing a taste aversive agent with a euthanasia formulation would result in a chemically compatible and chemically stable formulation.

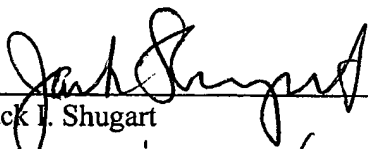
12. Baker, Minkoff, and Oshlack, the references that disclose using a taste aversive agent, do not disclose or suggest incorporating a taste aversive agent into a formulation that is intended for injection. There is no disclosure or suggestion by the cited references that a taste aversive agent would be compatible with a formulation intended for injection or of how a taste aversive agent would affect an animal's skin and veins when injected therewith.

13. The only cited reference that discloses or suggests using a taste aversive agent in a pharmaceutical setting is Oshlack, which teaches adding a taste aversive agent to an opioid analgesic. However, the chemical formulation of an opioid analgesic is quite different from the chemical formulation of a euthanasia formulation. Thus, just because a taste aversive agent is chemically compatible and chemically stable with an opioid analgesic does not imply or suggest to one of ordinary skill in the art that a taste aversive agent would be chemically compatible and chemically stable with an euthanasia formulation.

14. Numerous chemicals are not compatible with euthanasia formulations. For instance, as taught by the Sawyer '775 patent, in column 19, lines 40-50, using isopropyl alcohol in a euthanasia formulation provided undesirable effects. Accordingly, there is no reasonable expectation from the knowledge of a person of ordinary skill in the art that a taste aversive agent could be successfully incorporated into a euthanasia formulation.

15. It is important to delicately balance the chemicals in the euthanasia formulation so as not to cause an inhumane death, such as a prolonged death or unwanted side effects during the euthanizing process.

16. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Jack I. Shugart
Date: April 10/06